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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,609	07/25/2003	Etsuko Matsunaga	240944US0	9357

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EXAMINER
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HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/626,609

**Applicant(s)**

MATSUNAGA ET AL.

**Examiner**

Georgia L. Helmer

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

S.02

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 17 March 2005.
2. Applicant has cancelled claims 1-5 and added new claims 6-25. Claims 6-25 are pending, and are examined in the instant action.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112 second paragraph***

6. Claims 6-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record as applied to claims 1-5 in the Office Action of 17 December 2004, repeated in part below:

In claim 6, line 3,

- "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not

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appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired. All recitations of "gene" are also rejected.

Applicant traverses saying primarily (Response, p. 6) that "gene" refers to a segment of DNA that is involved in producing a polypeptide chain, which may optionally include regions receding and following the coding DNA as well as introns between the exons. Applicant's traversal is unpersuasive. Applicant has not defined the term "gene" in the specification to the terminology of Applicant's traversal.

In line 10, "redifferentiated" is confusing because no undifferentiated tissue is set forth.

Correction/clarification is required.

***Claim Rejections - 35 USC § 102***

7. Claims 6-12, 16, 17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Budar et. al., 1986, Plant Science, Vol 46, pages 195-206.

Applicant's invention is a method of producing transgenic plants comprising transforming a plant cell using a vector comprising a selectable marker gene comprising a gene encoding an enzyme which synthesizes auxin from an auxin precursor, culturing the transgenic cell in the presence of an auxin precursor/analogue and producing a transgenic plant therefrom, wherein the selectable marker gene comprises an *iaaH* gene, or an indoleacetamide hydrolase, and an isopentyl transferase or *ipt* gene.

Budar et. al. teach a method for producing a transgenic tobacco plant (p. 202, column 2, 1<sup>st</sup> full ¶) comprising (a) introducing a vector in a tobacco cell, wherein the vector is for gene introduction in a plant, comprising a desired gene and a selectable marker gene comprising a gene encoding an enzyme which synthesizes auxin from an auxin precursor, wherein the gene is *iaaH* (p. 199 – Figure III ) (b) culturing the plant cell into which the genes are introduced in the presence of an auxin precursor and/or analogue, wherein the auxin precursor is indoleacetamide (p. 202, 2<sup>nd</sup> & 3<sup>rd</sup> full ¶s), to prepare a redifferentiated tissue, and detecting and selecting the redifferentiated tissues, and (c) culturing the redifferentiated tissue selected in (b) to redifferentiate into a plant (p. 202, 2<sup>nd</sup> column 1<sup>st</sup> full ¶ ).

It is known in the art that *Agrobacterium* T-DNA gene 1 is the *iaaM* gene , gene 2 is the *iaaH* gene and gene 4 is the *ipt* gene. The *iaaM* gene catalyzes the production of tryptophan to indoleacetamide. This indoleacetamide is the substrate for the *iaaH* gene which catalyzes the production of indole acetic acid (IAA).

Budar et. al. also teach the use in the medium of IAA, NAA, indoleacetamide (p. 202, column 1, 2<sup>nd</sup> and 3<sup>rd</sup> full ¶ ), naphthaleneacetic acid amide, and the *iaaH* gene (gene 2) (p. 202 Table III). Budar et. al. further teach the vector being introduced using the plant bacterium *Agrobacterium*, and the vector comprising a kanamycin resistance gene.

Accordingly, Budar et. al. anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

8. Claims 6-12,13, 14, 15,16, 17, 18, 19, 20, 21, 22, 23, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budar et. al., 1986, Plant Science, Vol 46, pages 195-206, as cited above for claims 6-12, 16, 17, and 20) in view of Endo et al. (A new GST-MAT vector containing both isopentenyl transferase and iaaM/iaaH can produce marker-free transgenic tobacco plants with high frequency, Plant Cell Reports, 2002, Vol. 20, pages 923-928), applicant's admitted prior art , and Ebinuma et. al., US 5,965, 791, issued 12 October 1999.

The teachings of Budar et. al. are discussed above.

Budar et. al. do not teach the use of the ipt, a cytokinin synthesis gene, vector introduction via plant virus or a physical or chemical technique, a vector comprising a GUS or hygromycin resistance gene, or a sulfonyleurea resistance gene, or the use of the plant Eucalyptus or Populus as host.

Endo et teach the use of the ipt gene in combination with auxin producing genes to produce transgenic plants at higher frequency than with just the ipt gene alone (p.923, Abstract).

Applicant's admitted prior art (specification p. 5, 2<sup>nd</sup> & 3<sup>rd</sup> full ¶s) teaches that a vector can be introduced into a plant cell indirectly via a virus which infects a plant or directly by physical and chemical techniques.

Ebinuma et. al teach the use of a GUS gene, a hygromycin gene or a sulfonyleurea resistance gene as selectable markers in vectors for plant transformation

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(column 1, lines 51-53) as well as the use of Eucalyptus or Populus as hosts (column 11, lines 35-50) for plant transformation vectors .

Given the recognition of one of ordinary skill in the art of the value of transforming plants, especially woody plants such as Eucalyptus or Populus as taught by Ebinuma et. al , using transformation vectors containing selectable markers such as Hygromycin resistance, or sulfonyleurea resistance as taught by Ebinuma et. al., or markers comprising plant hormone genes such as ipt as taught by Endo et. al., and using various physical or chemical methods of vector introduction, one skilled in the art would have been motivated to substitute for the auxin genes of Budar et. al. the genes for auxin and cytokinin (ipt) synthesis of Endo, including the HygR and SU-R markers genes of Ebinuma et. al and to substitute for the tobacco of Budar et. al. the Eucalyptus or Populus of Ebinuma et. al. to achieve the promise of higher and more efficient transformation rates of high value woody plants, with a reasonable expectation of success.

9. Claim 25 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Endo et. al. Endo et. al. teach a vector comprising a selectable marker gene comprising an iaaH gene and isopentenyl transferase gene and the iaaM gene.

It would have well within the means of one skilled in the art to delete the iaaM gene from the vector of Endo et. al. , to produce the vector comprising iaaH and isopentenyl transferase genes, and lacking the iaaM gene. This would be motivated by the desirability of using simpler (fewer genes) vectors to optimize the growth conditions

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for phytohormones-requiring transgenic plants. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

Applicant traverses saying primarily (Response, p. 8) that the vector of their invention would result in better control over dedifferentiation of transformed plant cells when using with a medium containing an auxin precursor. Applicant's traversal is unpersuasive. Claim 25 is a product claim, not a method claim. Applicant argument is not in accord with the scope of the claim.

#### ***Remarks***

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later



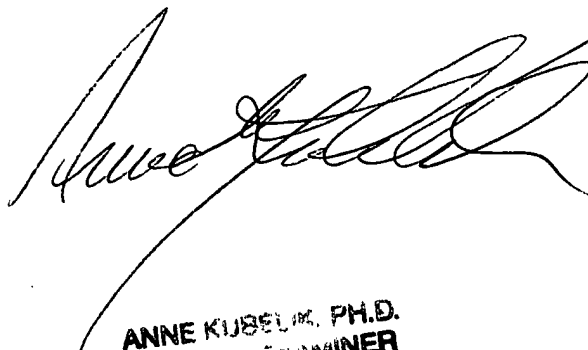
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than SIX MONTHS from the date of this final action. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-<sup>0796</sup>~~0076~~. The examiner can normally be reached on Monday-Thursday 10:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
August 9, 2005

  
ANNE KUSEL, PH.D.  
PRIMARY EXAMINER